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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,379	08/31/2001	Vince Phillips	5100-0705 0019-US	2153

23419 7590 10/07/2003

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EXAMINER	
HORLICK, KENNETH R	

ART UNIT	PAPER NUMBER
1637	7

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/945,379	Applicant(s) PHILLIPS ET AL.	
	Examiner Kenneth R Horlick	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,7-9,14-18 and 27-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7-9,14-18 and 27-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 4, 7-9, 14-18, and 27-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of GB 2 312 747 or Nadeau et al. (US 6,316,200), in view of Weiss et al. (US 6,207,392), and further in view of Bawendi et al. (US 2002/0160412).

These claims are drawn to a method for assaying for an amplification product, wherein the amplification product comprises a capture sequence whose complement is not present in the unamplified target polynucleotide (i.e., the capture sequence is provided during amplification), using a molecular beacon with a fluorophore/quencher labeling system attached to a microsphere, wherein the beacon target sequence is complementary to the capture sequence present in the amplification product, wherein a

first fluorophore is a semiconductor nanocrystal., and further wherein the microsphere comprises a spectral code.

GB 2 312 747 (see especially Figs. 11(a) and 11(b); pages 1-7; pages 12-13) and Nadeau et al. (see columns 3-11, especially column 7, lines 24-46 and the paragraph bridging columns 10 and 11) each disclose the claimed methods, except for use of a semiconductor nanocrystal as a label, as well as use of a spectral code to identify the label.

Weiss et al. disclose the use of semiconductor nanocrystals as fluorescent labels in nucleic acid assays (see especially columns 7, 12-13 and 16-28), including applications in energy transfer assays.

Bawendi et al. disclose the use of an encoding system, or "barcode", for use with semiconductor nanocrystals. One of the preferred embodiments is the use of such a system in the context of DNA identification and tracking. See especially abstract; paragraph [0013]; page 7 at paragraph [0057] to page 9, paragraph 0074].

One of ordinary skill in the art would have been motivated to modify the method of either one of the primary references by using one or more semiconductor nanocrystals as a fluorophore because Weiss et al. taught that such nanocrystals were advantageous fluorescent labels in nucleic acid assays. The skilled artisan would have been further motivated to apply a spectral code to the method of GB 2 312 747 or Nadeau et al., as modified by Weiss et al., because Bawendi et al. disclosed that such a code or barcode system was advantageous in identification and tracking of nucleic acids labeled with semiconductor nanocrystals. It would have been *prima facie* obvious

to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

2. With respect to the above rejection, the arguments of the response filed 07/10/03 (pages 7-8) have been fully considered, but are not found persuasive. The response argues that "Bawendi nowhere describes the use of a barcode in the context of an assay to detect an amplification product where a molecular beacon forms a stem-loop structure as claimed. No such assay is even hinted at and certainly not enabled by Bawendi. Accordingly, there is absolutely no suggestion or motivation to modify Bawendi as asserted, there is no reasonable expectation of success, and the references do not teach or suggest all of the claim limitations." The response further argues that the Office is using hindsight reconstruction in the rejection, and has failed to identify the requisite teaching or motivation from the prior art to arrive at applicants' invention.

None of these arguments are found convincing. Firstly, it is noted that the basis of the rejection is not modification of the Bawendi reference; rather, it is modification of the method of either of GB 2 312 747 or Nadeau et al. in view of Weiss et al., and further in view of Bawendi et al. In other words, all of the claim limitations except for use of a spectral code in the context of semiconductor nanocrystals, are covered in either of the primary references plus Weiss et al.; thus, Bawendi et al. is only relied upon for the teaching of such a spectral code, or barcode. The combination of the noted teachings is not merely hindsight reconstruction because, as pointed out in the

rejection, all of the teachings relate to the same context of nucleic acid detection. The rejection further states that motivation to use one or more semiconductor nanocrystals as a fluorophore comes from Weiss et al. which discloses these advantageous labels; and that motivation to apply a spectral code comes from Bawendi et al. which discloses that spectral codes are advantageous in identification and tracking of nucleic acids labeled with semiconductor nanocrystals. Put another way, both Weiss et al. and Bawendi et al. teach elements which would have been understood by the skilled artisan to provide fully expected advantages or benefits when applied to the method of one of the primary references. And given that all of the applied teachings are in the same context of nucleic acid detection, there clearly would have been reasonable expectation of success. So it is submitted that the above rejection satisfies all the requirements for establishing a proper case of *prima facie* obviousness.

3. No claims are free of the prior art.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kenneth R. Horlick, Ph. D.
Kenneth R Horlick
Primary Examiner
Art Unit 1637

10/01/03